

**REMARKS**

Claims 32, 34, 37, 39, 41, 42, 45-47, and 55-60 are currently pending in the present application, claim 44 having been canceled. New claims 58-60 have been added by the present amendment. Claims 32, 56 and 57 have been amended to replace "pyrogen-free" with "non-pyrogenic." Claim 55 has been amended to recite "wherein the antiseptic composition is packaged in a sterile, non-pyrogenic form." Support for these amendments can be found throughout the specification and at least at page 16, lines 22-23 of the present specification. Additionally, claims 32, 55 and 56 have been amended to express that the EDTA salt comprises "at least one of tri-sodium and tetra-sodium EDTA." Support for this amendment can be found throughout the specification and at least at page 14, lines 22-24. The benefit of using tri and/or tetra-sodium EDTA can be appreciated from considering the specification, such as Figures 1A-1D and Figure 2. Applicants note that the compositions defined in the claims of record may be formulated in a variety of ways and the techniques described in the specification are only illustrative. Claim 57 has been amended to express that the tri-sodium and tetra-sodium EDTA are in solution at a concentration sufficient to have antimicrobial activity. Support for this amendment can be found throughout the specification and at least at pages 13-14.

**§ 102(b) - Fahim**

Claims 55, 34, 41 and 42 stand rejected under 35 USC § 102(b) as allegedly being anticipated by Fahim (WO 00/13656). This rejection is respectfully traversed.

Fahim does not teach or suggest each feature of the present invention, as set forth in amended representative claim 55. For example, Fahim does not teach or suggest that the antiseptic composition is packaged in a sterile, non-pyrogenic form. Moreover, the Office recognizes, at page 6 of the August 26, 2005, Office Action, that "Fahim does not specifically teach that the composition is packaged in a sterile pyrogen free form." Applicants assert that the limitation of "packaged in a sterile, non-pyrogenic form" also overcomes Fahim.

Accordingly, applicants respectfully request that the rejection of claims 55, 34, 41 and 42 under § 102(b) as anticipated by Fahim, be withdrawn.

§ 102(b) - Kurginski

Claims 55, 34, 41 and 42 stand rejected under 35 USC § 102(b) as allegedly being anticipated by Kurginski (GB 1 279 148). This rejection is respectfully traversed.

Kurginski does not teach or suggest each feature of the present invention, as set forth in amended representative claim 55. For example, Kurginski does not teach or suggest that the antiseptic composition is packaged in a sterile, non-pyrogenic form. Moreover, the Office recognizes, at page 2 of the August 26, 2005, Office Action, that the limitation of "packed in a sterile, pyrogen-free form" overcomes Kurginski as a § 102(b) reference. Applicants assert that the limitation of "packaged in a sterile, non-pyrogenic form" also overcomes Kurginski.

Accordingly, applicants respectfully request that the rejection of claims 55, 34, 41 and 42 under § 102(b) as anticipated by Kurginski, be withdrawn.

§ 103(a) – Fahim in view of Wider

Claims 32, 39, 44, 45, and 56-57 stand rejected under 35 USC § 103(a) as allegedly being obvious over Fahim (WO 00/13656) in view of Wider (US 6,500,861). This rejection is respectfully traversed.

As addressed above, Fahim does not teach or suggest that the antiseptic composition is packaged in a sterile, non-pyrogenic form.

The Office relies on Wider to allegedly remedy this deficiency, arguing that it would have been obvious to one skilled in the art to employ the composition of Fahim in a sterile, pyrogen-free condition because Wider allegedly teaches antimicrobial compositions packaged in a sterile, pyrogen-free form.

However, one skilled in the art would not have been motivated to incorporate the teachings of Wider into the composition of Fahim.

Representative claims 32, 56 and 57 recite that the compositions are packaged in a sterile, non-pyrogenic form. Because the compositions are packaged in a sterile, non-pyrogenic form, the compositions may be safe and biocompatible, at least in modest volumes in a patient's bloodstream. Providing compositions packaged in a sterile, non-pyrogenic form typically requires special processing procedures for both packaging components and solution components. These

procedures can be expensive and time consuming. For example, care must be taken with regard to multiple potential sources for pyrogens, e.g., water used as a solvent or in processing, packaging components, raw materials, and equipment used.

The Office cites from Wider a peritoneal dialysis fluid that is described as sterile and pyrogen free. See Wider, column 6, lines 5-11. Peritoneal dialysis fluid is introduced into the peritoneal cavity, which is the space inside the smooth membrane that lines the abdomen (peritoneal membrane, or peritoneum). The organs of the abdomen and pelvis, such as the stomach and large intestine, are contained in the peritoneal cavity.

Fahim, on the other hand, is focused on an antimicrobial handwash composition. See, e.g., Abstract and Field of Invention ("the invention relates to liquid antimicrobial handwash compositions").

One skilled in the art would not be motivated by the teaching of a sterile, pyrogen-free dialysis fluid to modify a handwash. A handwash is not intended for potential contact with a patient's bloodstream or to otherwise be possibly introduced into a patient's body. A handwash is simply meant to cleanse the skin. Thus, there is no reason for one skilled in the art to package a handwash in a sterile, non-pyrogenic form because, for example, a handwash does not typically come into contact with a user in a manner where packaging in a sterile, non-pyrogenic form would be beneficial. One skilled in the art would not be motivated by a teaching of a sterile, pyrogen-free dialysis fluid to then undergo the extra time and expense to package a handwash in a sterile, non-pyrogenic form.

Accordingly, applicants respectfully request that the rejection of claims 32, 39, 44, 45, and 56-57 under § 103(a) as being obvious over Fahim in view of Wider, be withdrawn.

§ 103(a) – Fahim in view of Wider and further in view of Root et al.

Claim 47 stands rejected under 35 USC § 103(a) as allegedly being obvious over Fahim (WO 00/13656) in view of Wider (US 6,500,861) and further in view of Root et al. This rejection is respectfully traversed.

As addressed above, one skilled in the art would not be motivated by Wider to modify Fahim in order to arrive at the presently claimed invention.

Without admitting the propriety of the alleged combination, applicants note that Root et al. does not remedy the deficiencies of Fahim in view of Wider as applied to claims 32, 39, 44, 45, and 56-57. For example, Root et al. does not teach or suggest that the hand wash of Fahim should be packaged in a sterile, non-pyrogenic form.

Accordingly, applicants respectfully request that the rejection of claim 47 under § 103(a) as being obvious over Fahim in view of Wider and further in view of Root et al., be withdrawn.

§ 103(a) – Fahim in view of Wider and further in view of Remington's Pharmaceutical Sciences

Claim 46 stands rejected under 35 USC § 103(a) as allegedly being obvious over Fahim (WO 00/13656) in view of Wider (US 6,500,861) and further in view of Remington's Pharmaceutical Sciences. This rejection is respectfully traversed.

As addressed above, one skilled in the art would not be motivated by Wider to modify Fahim in order to arrive at the presently claimed invention.

The Examiner relies on excerpts from Remington's Pharmaceutical Sciences, teaching a pyrogen free solution of sodium chloride and that hypodermic syringes are used for injection of liquids. See Remington's Pharmaceutical Sciences, page 835, column 2, and page 1837. The sodium chloride solution is disclosed to be a electrolyte replenisher administered intravenously.

Fahim, on the other hand, is focused on an antimicrobial handwash composition. See, e.g., Abstract and Field of Invention ("the invention relates to liquid antimicrobial handwash compositions").

One skilled in the art would not be motivated by the teaching of a sterile, pyrogen-electrolyte replenisher to modify a handwash. A handwash is again not intended for potential contact with a patient's bloodstream or to otherwise be possibly introduced into a patient's body. A handwash is simply meant to cleanse the skin. Thus, there is no reason for one skilled in the art to package a handwash in a sterile, non-pyrogenic form because, for example, a handwash does not typically come into

contact with a user in a manner where packaging in a sterile, non-pyrogenic form would be beneficial. One skilled in the art would not be motivated by a teaching of a sterile, pyrogen-free electrolyte replenisher to then undergo the extra time and expense to package a handwash in a sterile, non-pyrogenic form.

Accordingly, applicants respectfully request that the rejection of claim 46 under § 103(a) as being obvious over Fahim in view of Wider and further in view of Remington's Pharmaceutical Sciences, be withdrawn.

§ 103(a) – Kurginski in view of Fahim and in view of Wider

Claims 32, 37, 44, 45, and 56-57 stand rejected under 35 USC § 103(a) as allegedly being obvious over Kurginski (GB 1 279 148) in view of Fahim (WO 00/13656) and in view of Wider (US 6,500,861). This rejection is respectfully traversed.

As recognized by the Office, Kurginski does not teach or suggest that the antiseptic composition is packaged in a sterile, non-pyrogenic form.

The Office relies on Fahim and Wider to allegedly remedy this deficiency, alleging that it would have been obvious to one skilled in the art to employ the composition of Fahim in a sterile, pyrogen-free condition because Wider allegedly teaches antimicrobial compositions packaged in a sterile, pyrogen-free form.

However, one skilled in the art would not have been motivated to incorporate the teachings of Wider into the composition of Fahim.

The Office cites from Wider a peritoneal dialysis fluid that is described as sterile and pyrogen free. See Wider, column 6, lines 5-11. Peritoneal dialysis fluid is introduced into the peritoneal cavity, which is the space inside the smooth membrane that lines the abdomen (peritoneal membrane, or peritoneum). The organs of the abdomen and pelvis, such as the stomach and large intestine, are contained in the peritoneal cavity.

Fahim, on the other hand, is focused on an antimicrobial handwash composition. See, e.g., Abstract and Field of Invention ("the invention relates to liquid antimicrobial handwash compositions").

One skilled in the art would not be motivated by the teaching of a sterile, pyrogen-free dialysis fluid to modify a handwash. A handwash is not intended for

potential contact with a patient's bloodstream or to otherwise be possibly introduced into a patient's body. A handwash is simply meant to cleanse the skin. Thus, there is no reason for one skilled in the art to package a handwash in a sterile, non-pyrogenic form because, for example, a handwash does not typically come into contact with a user in a manner where packaging in a sterile, non-pyrogenic form would be beneficial. One skilled in the art would not be motivated by teaching of a sterile, pyrogen-free dialysis fluid to then undergo the extra time and expense to package a handwash in a sterile, non-pyrogenic form.

Kurginski is focused on "a cleaning composition useful for releasing the particular soils that tend to accumulate in toilets and similar sanitary facilities." Kurginski, page 1, lines 12-15. One skilled in the art would not be motivated to package such a cleaning solution in a sterile, non-pyrogenic form. The cleaning solution is not intended for potential contact with a patient's bloodstream or to otherwise be possibly introduced into a patient's body and there is no motivation to package such a cleaning solution the compositions in a form that is sterile and non-pyrogenic. One skilled in the art would not be motivated by a teaching of a sterile, pyrogen-free dialysis fluid to then undergo the extra time and expense to package a cleaning solution in a sterile, non-pyrogenic form.

Accordingly, applicants respectfully request that the rejection of claim 46 under § 103(a) as being obvious over Kurginski in view of Fahim and in view of Wider, be withdrawn.

### Summary

From a review of each of the combinations of prior art documents, it is evident that the Office has studied applicants' claims, found isolated teachings in the art and attempted to piece them together in an attempt to meet the claimed subject matter. This is manifestly improper as noted by decisions such as *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991) which caution that "The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure."

At best, the Office could take the position that it would be obvious to try the combination of prior art documents in the manner hypothesized in the Official Action.

However, "obvious to try" is not the standard under 35 U.S.C. §103 as has been held by numerous decisions such as *In re Goodwin*, 198 USPQ 1 (CCPA 1978) and *In re Geiger*, 2 USPQ2d 1276 (Fed. Cir. 1987). The factual situation in the *Goodwin* decision provides greater insight into this issue. In that case, one aspect of the claimed subject matter was a method of manufacturing glass which used carbon monofluoride to provide relatively permanent lubrication. The Examiner had rejected the claims over two patents, one of which described a glass manufacturing method using lead compounds as lubricants and another (i.e., Margrave) which disclosed carbon monofluorides useful as solid lubricants, but not in a glass manufacturing method. In reversing the rejection, the Court stated: "At best, the PTO has shown evidence that it would have been obvious to the skilled artisan to try Margrave's carbon monofluorides. However, this Court has consistently refused to recognize "obvious to try" rejections." (Citations omitted at page 3) Accordingly, using similar standards and logic, it is without question that the §103 rejections cannot be maintained.

#### New Claims

Claims 58-60 have been added by the present amendment. Support for claims 58 and 59 may be found throughout the specification and at least at page 15, lines 15-18. Support for claim 60 may be found throughout the specification and at least at page 13, lines 6-16. Claims 58-60 are patentable for at least the reasons claims 32, 55, and 56 and claim 57 are patentable, respectively.

Moreover, with regard to claims 58 and 59, Fahim teaches an antimicrobial composition comprising at least three antimicrobials (triclosan, PCMX and gluteraldehyde), wherein EDTA is not even required. See, e.g., Fahim, pages 8-9. While EDTA may "enhance" the antimicrobial activity of the three component antimicrobial composition, it clearly does not provide at least 50% of a total antimicrobial activity of the composition.

Similarly, Kurginski teaches a toilet cleanser with a germicide, wherein EDTA is simply added as a chelating agent. See, e.g. Kurginski, page 3, lines 74-111. There is no recognition of any antimicrobial activity for the EDTA, much less the claimed level of antimicrobial activity.

Thus, applicants respectfully submit that claims 58 and 59 are even further patentable over the cited prior art.


Conclusion

In view of the foregoing, further and favorable consideration of the subject application in the form of a Notice of Allowance is respectfully requested.

If there are any questions concerning this response, or the application in general, the Examiner is respectfully requested to telephone applicant's undersigned representative so that prosecution may be expedited.

Respectfully submitted,  
BUCHANAN INGERSOLL PC

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By:   
Travis D. Boone  
Registration No. 52,635

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(703) 836-6620